UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS INC., MYLAN SPECIALTY L.P., AND MYLAN INC., Plaintiffs, v. SANOFI-AVENTIS U.S. LLC, SANOFI S.A., AVENTIS PHARMA S.A., AND SANOFI-AVENTIS PUERTO RICO INC. Defendants.	Civil Action No. 23-836-MRH

MEMORANDUM IN SUPPORT OF THE FEDERAL TRADE COMMISSION'S MOTION FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE*

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The Federal Trade Commission respectfully moves for leave to file an *amicus curiae* brief in the above-captioned matter in connection with Defendant Sanofi's pending motion to dismiss.[1] Mylan does not oppose the FTC's filing of an *amicus* brief and Sanofi consents to the FTC's filing of an *amicus* brief.

This case involves allegations that Sanofi monopolized the market for injectable insulin glargine in part by abusing an FDA regulatory process. Under the Hatch-Waxman Act, a company marketing a branded drug under a New Drug Application (NDA) must list certain patents that claim either the drug or a "method of using" that drug in an FDA database known as the Orange Book. But it cannot list other types of patents, even if they might be infringed by a competing drug. This limitation is important because listing a patent in the Orange Book and subsequently filing an infringement suit against a 505(b)(2) applicant like Mylan triggers an automatic 30-month stay of FDA approval for the competitor's product. When an Orange Book patent is appropriately listed, this stay reflects Congress's intent to provide brand pharmaceutical companies with an incentive to develop new drugs and new methods of treatment. But if a brand company obtains the stay by listing and enforcing a patent that does not meet Orange Book criteria, this does not reflect the intended incentive and instead simply blocks competition that would lower health care costs and benefit patients. If Sanofi's patent listings were improper and harmed the competitive process, they may constitute illegal monopolization.

The FTC seeks leave to submit a brief as *amicus curiae* to assist the Court with its review of the motion to dismiss. The FTC is an independent agency charged by Congress with enforcing competition and consumer protection laws.[2] It exercises primary responsibility over federal

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[1] Defendant Sanofi-Aventis U.S., LLC's Mot. to Dismiss, *Mylan Pharmaceuticals Inc. v. Sanofi-Aventis U.S. LLC*, No. 2:23-cv-00836.

[2] 15 U.S.C. §§ 41–58.

antitrust enforcement in the pharmaceutical industry. The FTC has substantial experience addressing the impact of the Hatch-Waxman Act on competition for pharmaceuticals.[3] In addition to conducting investigations and enforcement actions in its role as a law enforcement agency, the FTC has a congressionally-mandated role to conduct studies of industry-wide competition issues.[4] It has conducted numerous studies covering the pharmaceutical industry, including reports on generic competition under the Hatch-Waxman Act, which have been cited by numerous courts including the Supreme Court and the Third Circuit.[5]

The FTC has also taken actions specifically related to improper Orange Book patent listings, including a study, an enforcement action, and multiple amicus briefs.[6] In light of this expertise, as well as the FTC's mandate to protect competition and the public interest, we respectfully request that the Court accept the attached proposed *amicus* brief which explains the

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[3] *See, e.g.*, *FTC v. Actavis, Inc*., 570 U.S. 136 (2013); *Impax Labs., Inc. v. FTC*, 994 F. 3d 484 (5th Cir. 2021); *FTC v. AbbVie Inc*., 976 F.3d 327, 339 (3d Cir. 2020); *FTC v. Shkreli*, 581 F. Supp 3d 579 (S.D.N.Y. 2022); *King Drug Co. of Florence v. Cephalon, Inc.*, 88 F. Supp. 3d 402 (E.D. Pa. 2015). For a fuller summary of the FTC's actions in the pharmaceutical industry, *see also Overview of FTC Actions in Pharmaceutical Products and Distribution* (October 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Overview-Pharma.pdf.

[4] 15 U.S.C. § 46(b) (granting the FTC authority to gather information for industry-wide studies, apart from the Commission's authority to gather information related to specific discrete law enforcement investigations).

[5] *See, e.g.*, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 408 (2012) (citing an FTC study on generic pharmaceuticals); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 396 (2006) (Kennedy, J., concurring) (citing an FTC study on the proper balance between competition and patent law); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 754 n.11, 765 n.20 (1976) (referring to an FTC study concerning drug price advertising restrictions); *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 208, 215 (3d Cir. 2012) (citing statistics from FTC studies on Hatch-Waxman patent litigation and settlement).

[6] *See* Generic Drug Entry Prior to Patent Expiration: An FTC Study, at 39-52 (2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf; Decision and Order, *In re Biovail Corp*., FTC Dkt. No. C-4060 (Oct. 2, 2002); Mem. of Law for the Fed. Trade Comm'n as *Amicus Curiae* Opposing Defendant's Mot. to Dismiss, *In re: Buspirone Patent Litig.*, No. 1:01-md-1410-JGK (S.D.N.Y. Jan. 8, 2002) (Doc. No. 31).

significant harm improper Orange Book listings can cause to consumers.

I. District Courts Have Broad Discretion to Appoint an *Amicus Curiae*

"District courts have broad discretion to appoint amicus curiae."[7] "Although there is no rule governing the appearance of an *amicus curiae* in the United States District Courts," some district courts in the Third Circuit have looked to the Federal Rules of Appellate Procedure for guidance in exercising their broad discretion.[8] In most circumstances, Appellate Rule 29 allows federal agencies to file amicus briefs in the Court of Appeals as a matter of right. This reflects the fact that federal agencies offer a distinct perspective: "governmental bodies, acting as amicus curiae, possess unparalleled institutional expertise and constitute a valuable means of determining how the court's decision may affect the world outside its chambers."[9]

District courts in this Circuit have also applied a four-part standard that incorporates principles similar to Rule 29 as well as other factors, including one considering the "partiality" of the would-be *amicus*.[10] These courts grant leave to participate as *amicus curiae* when: "(1) the petitioner has a 'special interest' in the particular case; (2) the petitioner's interest is not represented competently or at all in the case; (3) the proffered information is timely and useful; and (4) the petitioner is not partial to a particular outcome in the case." *See, e.g.*, *Liberty Res.*, 395 F. Supp. 2d at 209.

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[7] *Sciotto v. Marple Newtown Sch. Dist.*, 70 F. Supp. 2d 553, 554 (E.D. Pa. 1999) (quoting *Liberty Lincoln Mercury, Inc. v. Ford Mktg. Corp.*, 149 F.R.D. 65, 82 (D.N.J. 1993)); *see also Avellino v. Herron*, 991 F. Supp. 730, 732 (E.D. Pa. 1998).

[8] *United States v. Alkaabi*, 223 F. Supp. 2d 583, 592 (D.N.J. 2002).

[9] Michael K. Lowman, *The Litigating Amicus Curiae: When Does the Party Begin After the Friends Leave?*, 41 AM. U. L. REV. 1243, 1261–62 (1992).

[10] *See, e.g.*, *Liberty Res., Inc. v. Phila. Hous. Auth.*, 395 F. Supp. 2d 206, 209 (E.D. Pa. 2005) (citing *Sciotto*, 70 F. Supp. 2d at 555); Order, *Prof. Drug. Co. Inc. v. Wyeth Inc.* (*In re Effexor XR Antitrust Litig.*), No. 3:11-cv-05479-JAP-LHG (D.N.J. Oct. 3, 2012) (Doc No. 187).

II. This Court Should Exercise Its Discretion to Accept the FTC's *Amicus* Brief

The FTC respectfully requests that the court exercise its discretion to accept its *amicus* brief because (1) the brief expresses both public and governmental interests of a federal agency charged with protecting consumers from unfair competition; (2) these interests are not currently represented before the Court; (3) the information proffered is useful and timely; and (4) the FTC is not partial to any specific outcome in the case.

First, the FTC is a federal agency representing the public interest with the goal of preserving competition and protecting consumers from violations of the antitrust laws. As outlined in the FTC's *amicus* brief, allegations that brand firms have inappropriately listed patents in the Orange Book to obtain a 30-month stay of competition may have serious long-term implications for *all* consumers, not just the private parties in this matter. Moreover, as an agency charged by Congress with enforcing competition laws, and as the primary antitrust enforcer in the pharmaceutical industry, the FTC has a special interest in the interpretation of laws impacting generic drug competition. District courts consider these interests when granting motions for leave to federal agencies to participate as *amicus curiae*.[11]

Second, the FTC's interest, and the interest of consumers in general, may not be adequately represented by the private parties to this litigation because each of the parties is charged with representing its own interests. Unlike the parties, whose interests are focused on the outcome of this particular case, the Commission has broader interests in the proper use of the Orange Book listing process and the potential ramifications for consumers of prescription drugs when this framework is abused. The FTC's unique perspective as a government agency may aid

[11] *See, e.g.*, *Waste Mgmt. of Pa., Inc. v. City of York*, 162 F.R.D. 34, 37 (M.D. Pa. 1995) (stating as a basis for accepting an *amicus* brief that "the EPA has a special interest in this litigation as it is the primary body responsible for administering and enforcing" the relevant law).

the court in its analysis of the issues in this case.[12]

Third, the brief provides useful information based on the FTC's extensive knowledge of pharmaceutical competition. As described in the *amicus* brief, the FTC has a unique institutional perspective—based on years of study and empirical analysis of pharmaceutical markets—to offer the Court in its analysis of the competitive implications of the allegations raised in this case. The *amicus* brief outlines the relevant regulatory structure and explains how the regulatory setting may influence antitrust analysis. The FTC's brief is timely because it is filed within seven days of Mylan's filing on November 13, 2023, and provides ample time for Sanofi to respond.

Fourth, while the FTC is interested in the development of the law in this area, it takes no position on the ultimate outcome in this case. The FTC's *amicus* brief explains the FTC's views of the governing regulatory structure and argues that improper listings can cause serious harm to competition and consumers. As such, improperly listing a patent in the Orange Book can constitute illegal monopolization or part of an illegal course of monopolistic conduct under Section 2 of the Sherman Act. The FTC takes no position on whether the Sanofi patents at issue were improperly listed. Thus, while the FTC is partial in the sense of its clearly expressed interest in protecting consumers, it is not partial in the sense of expressing a view on which party

[12] *See, e.g.*, *Avellino*, 991 F. Supp. at 732 (granting leave for motion to file *amicus* brief because it "will aid the Court in its understanding of the issues before it"). Several district courts in this circuit have accepted FTC *amicus* briefs on matters related to competition in the pharmaceutical industry. *See* Order, *Sage Chem., Inc. v. Supernus Pharms., Inc.,* No. 1:22-cv-1302-CJB (D. Del. Mar. 20, 2023) (Doc. No. 92); Order, *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC,* No. 1:21-cv-691-GBW (D. Del. Nov. 15, 2022) (Doc No. 226); Order, *Mylan Pharms., Inc. v. Celgene Corp.*, No. 2:14-cv-02094-ES-MAH (D.N.J. June 24, 2014) (Doc. No. 30); Min. Entry, *Actelion Pharms. Ltd. v. Apotex*, *Inc.*, No. 1:12-cv-5743-NLH (D.N.J. Oct. 17, 2013) (Doc. No. 92); Order, *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 2:12-cv-00995-WHW-MCA (D.N.J. Nov. 7, 2012) (Doc. No. 100); *but see* Order, *Prof. Drug Co.*, No. 3:11-cv-05479-JAP-LHG, (D.N.J. Oct. 3, 2012) (Doc. No. 187) (denying the FTC's motion for leave to file an *amicus* brief).

should ultimately prevail in the litigation.[13]

III. Conclusion

For the foregoing reasons, the Commission respectfully requests that the Court grant leave to file an *amicus curiae* brief.

Dated: November 20, 2023

Respectfully submitted,

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[13] As Justice Alito observed when he sat on the Third Circuit, "it is not easy to envisage an amicus who is 'disinterested' but still has an 'interest' in the case." *Neonatology Assocs., P.A. v. Comm'r of Internal Revenue*, 293 F.3d 128, 131 (3d Cir. 2002) (citing Rule 29's requirement that an amicus must state its interest in the case). Then-Judge Alito concluded that requiring an *amicus* to be fully impartial "became outdated long ago."